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13. ABSTRACT ***(Maximum 200 Words)***

The Operating Room of the Future will deliver the optimal surgical environment through the integration of people, equipment, space and process. The Computer Assisted Minimally Invasive Surgery (CAMIS) project has completed the development and deployment of a number of components critical to the achievement of The Operating Room of the Future concept. The first component is a Digital Micro Encoscope (DME). This device provides endoscopic visualization of orthopaedic joint spaces. Coupled with its integrated video processing components, the DME enables a medical diagnosis of possible orthopaedic abnormalities through an incision size less than 2mm. The second component of the CAMIS project is a Patient Resource Database (PRD). This system constitutes a surgical data collection system coupled with a search mechanism which integrates other hospital data repositories into a unified interface. The system is referred to as the Electronic Surgical Record (ESR) and functions like an Operating Room "aeronautical black box" recording critical aspects of the ensuing procedure. The third component of the CAMIS project is a Personal Surgical Display (PSD). This component provides the user with an augmented reality display of patient data during the performance of a surgical procedure. The design of the system enables a see through capability which allows the physician to reference their patient with respect to any data that is shown.

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FOREWORD

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PI - Signature Date

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INTRODUCTION

Computer Assisted Minimally Invasive Surgery (CAMIS) refers to the application of computer technology to the practice of minimally inavsive surgery. We are developing those tools necessary to enable the Operating Room of the Future. This Room can be located anywhere that the surgeon and(or) patient are(is) located. One such tool is a Digital Micro-Endoscope (DME). This device can be inserted into the body through a needle-sized puncture yet it provides visualization of internal structures comparable to a much larger endoscope. Another device developed is a Patient Resource Database (PRD). This device provides a one-stop interface to the patient's medical history and a mechanism for recording additional information about the treatment being delivered. This device is interfaced through a commonly available Hyper-Text Markup Language (HTML) viewer and consequently provides an intuitive interface for the operator. Another device developed is a Personal Surgical Display (PSD). This device provides a body-worn visual interface to both the DME and the PRD. The wearer of this device enjoys an immersive display of their patient's condition both past and present.

BODY

Digital Micro-Endoscope (DME)

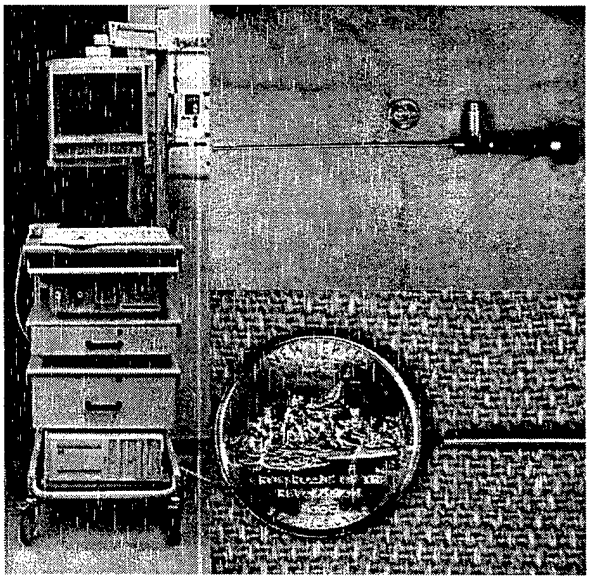
Traditional surgical endoscopes require a relatively large incision (4-10mm) which must be made while the patient is completely anesthetized. This logistical constraint recquires the use of a traditional operating in the event of a complication related to the anesthesia. We proposed the development of a micro-endoscope that could provide the visualization of a traditional endoscope but the operational freedom to be used as you would a syringe. To obtain the clarity of a 5mm endoscope while using a 2mm version we developed a digital processing system that would improve the quality of the resulting video signal and display an image that is clinical significant.

Key Task Steps

1. Identify the clinical requirements of the DME.
2. Establish the testing benchmarks for comparison to traditional endoscopes.
3. Contract the development of a prototype fiber optic endoscope
4. Identify the limitations of the prototype fiber optic endoscope
5. Develop the algorithms necessary to improve the fiber optic video image.
6. Contract the development of a computer based image enhancement system utilizing the developed algorithms.
7. Evaluate the prototype fiber optic endoscope with the digital image enhancement system.
8. Contract the development of second generation fiber optic endoscopes and digital image enhancement system to enable further clinical testing.
9. Perform clinical evaluation.

Final Results

A second generation system was delivered during the last period of the project. It addressed deficiencies noted in the earlier delivered system. The most significant of these was the quality of the intra-procedureal video displayed. The first system provided enhanced video which demonstrated a proof of concept as to the useability of a small diameter endoscope. Unfortunately there were visual artifacts in this system which were psychological unplesant and diminished the overall functionality of the device. The second generation system addressed these artifacts and the overall end result met our design criteria of visual equivalence to a 5mm arthroscope.



Patient Resource Database (PRD)

The information that is collected both before and during surgery is often presented in several disparate formats. Image data is typically displayed using large film sheets while blood pressure and respiration information is presented on an analog display. Further, instrument position is determined using ionizing radiation devices and this information is presented using video displays. Several surgical instruments produce video images that must also be displayed. All of this information and its associated display technology will be corralled into a single display processor that will enable the concise presentation of these data using the PSD. The enabling capability of this development will be the ability to combine information in a way that allows it to work together. Presenting the instrument position along with the video image that the instrument generates will enable the surgeon to better use the instrument, which in turn will generate a better image. We propose the development of a multi-modality information processor capable of accepting inputs of video, digital image data and real-time instrument sensing. This device will accept these inputs both before and during surgery and make them available to the PSD when commanded.

Key Task Steps

1. Identification of clinical requirements for PRD
2. Establishment of technical specifications for PRD
3. Evaluation of hardware components
4. Selection of interface methodology
5. Design of core data storage system
6. Design of remote data access interface
7. Design of Physician interface
8. Independent Testing/Evaluation of Physician interface
9. Selection of final user interface
10. Implementation of remote data access system
11. Implementation of local data access system
12. Implementation of user interface
13. Testing/Evaluation of data access system
14. Testing/Evaluation of combined patient resource system
15. Identification of deficiencies for evaluated system
16. Modifications of PRD identified
17. Delivery of final PRD for clinical use

Final Results

The PRD system has been deployed in several surgical venues within The Cleveland Clinic Health System. These include Minimally Invasive Surgery Operating Rooms, General Surgery Operating Rooms, Neurological Surgery Operating Rooms and Ambulatory Surgical Center Procedure Rooms. It is anticipated that a Military Health System deployment will occur at some point in the future but no definite program has been established.

Radiology – A DICOM interface has been developed between the SIEMENS Medical Systems Magic Store™, family of DICOM compatible devices. In principle this interface will be compatible with any

DICOM device but this has not been confirmed. This interface allows for the retrieval of DICOM data from Radiology into the PRD system. This has been a significant advance in the way surgeon's review their patient's radiological images and has obviated the need to locate hard copy films for use in the operating room.

Laboratory – A Sockets™ interface has been developed to allow the transmission of laboratory images into the PRD. From a computer that contains images of interest the user can use the interface to establish a communication channel to the PRD which is then used to upload the data.

Operating Room - A Network Video Capture device has been developed to allow the acquisition and transmission of surgical video information to the PRD. These devices are deployed at both the main hospital campus and some of its satellite ambulatory surgery centers.

Office – An Email interface has been developed to allow the receipt of patient specific information into the PRD. The user can attach data files to a message that they compose and with the proper identification this information will be entered into the patient's record.

The user interface requires a Hyper-Text Markup Language (HTML) viewer such as Netscape™ or Microsoft Internet Explorer™. Once the users computer has been authorized they are able to search by hospital record number for all data available. The data is organized by medical exam and identified by the date and specific protocol performed, as shown in Figure 2.

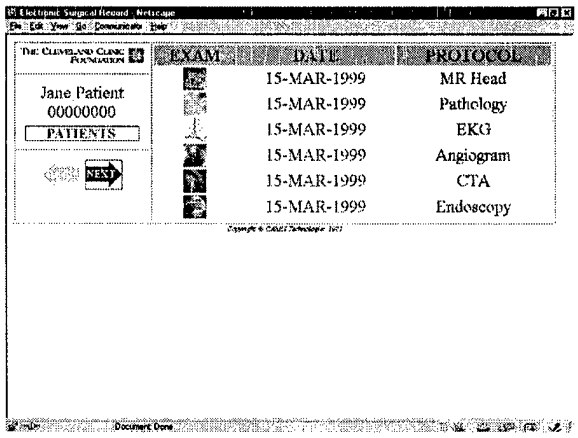


Figure 2

Further information regarding the design of the PRD can be found in the U.S. Provisional Patent application for the Electronic Surgical Record. This application has been attached as Appendix A.

Personal Surgical Display (PSD)

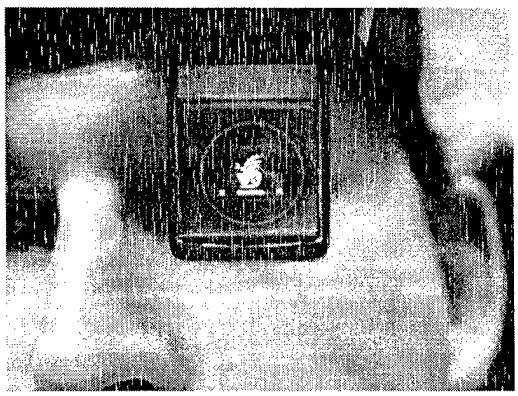
Many devices have been developed for use in an operating room environment that display data about a patient's condition. Few devices have been developed to present the relevant information that a surgeon requires in a concise fashion. Pilots have used head mounted displays to provide mission critical information in an intuitive format for some time and we propose to use such a display to immerse the surgeon in the data that is collected before and during a surgical procedure. We propose the development of a binocular head worn display capable of presenting two different computer generated images at a display resolution of 800x600 pixels with full color. This display will be worn by the surgeon during a procedure and enable the presentation of information in stereo along with the ability to view the operative field when necessary. The information presented will be controlled through the use of voice directed instructions from a discrete collection of commands. These commands will enable the modification in the way information is displayed along with its type and origin. This Personal Surgical Display (PSD) will be light in weight and capable of being used in any operating room at our hospital. The PSD will be the single source of patient information for the surgeon and enable certain procedures that require computer-assisted control.

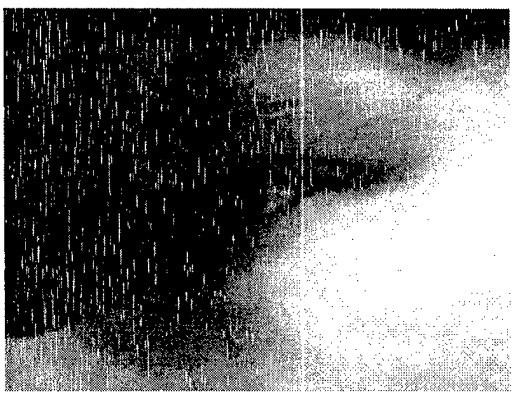
Key Task Steps

1. Identification of clinical requirements for PSD
2. Establishment of technical specifications for PSD
3. Selection of at least three clinical prototypes for further evaluation
4. Procurement of prototypes for clinical testing
5. Identification of deficiencies for evaluated PSD
6. Selection of final PSD design
7. Procurement of final PSD for clinical use

Final Status

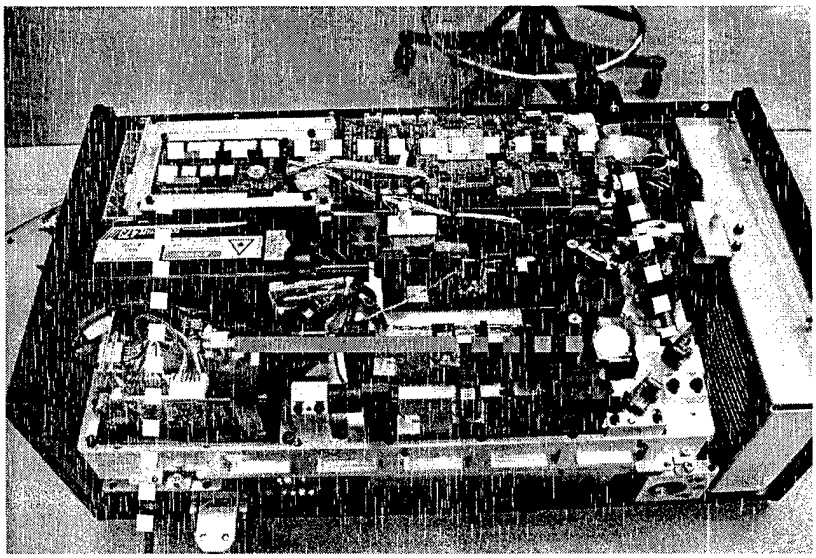
After much evaluation and discussion we agreed to select the Microvision Virtual Retinal Display (VRD) as the component provider to the PSD device. The key functional criteria was the ability to look through the display and as a result not impair the view of the operator. Although there were other potential solutions they either required the viewer to avert their eyes slightly or be occluded all together. In a clinical environment, a clear view of the clinical site is paramount. The Microvision VRD provided the added capability of superimposition of a clinical site with a video generated view. This visual augmentation was the key to its selection. Delivery of a full color VRD was delayed





beyond the original termination of the CAMIS project. We requested and were granted two extensions of the project in order to adequately report on the results of the device.

Our impressions have been very favorable regarding the VRD technology. The implementation is still a little cumbersome and the production cost must still be reduced for widespread market penetration. The video quality of the VRD system is superb and represents the best in class when it comes to visual representation of anatomical objects.



KEY RESEARCH ACCOMPLISHMENTS

- Development of a 2mm endoscope with visualization comparable to a 5mm endoscope.
- Development of an HTML based search engine for patient medical records
- Development of an Operating Room Data Collection system for automated recording of relevant events.
- Application of a full color, see through, retinal display system capable of visual augmentation of a clinical procedure with patient data

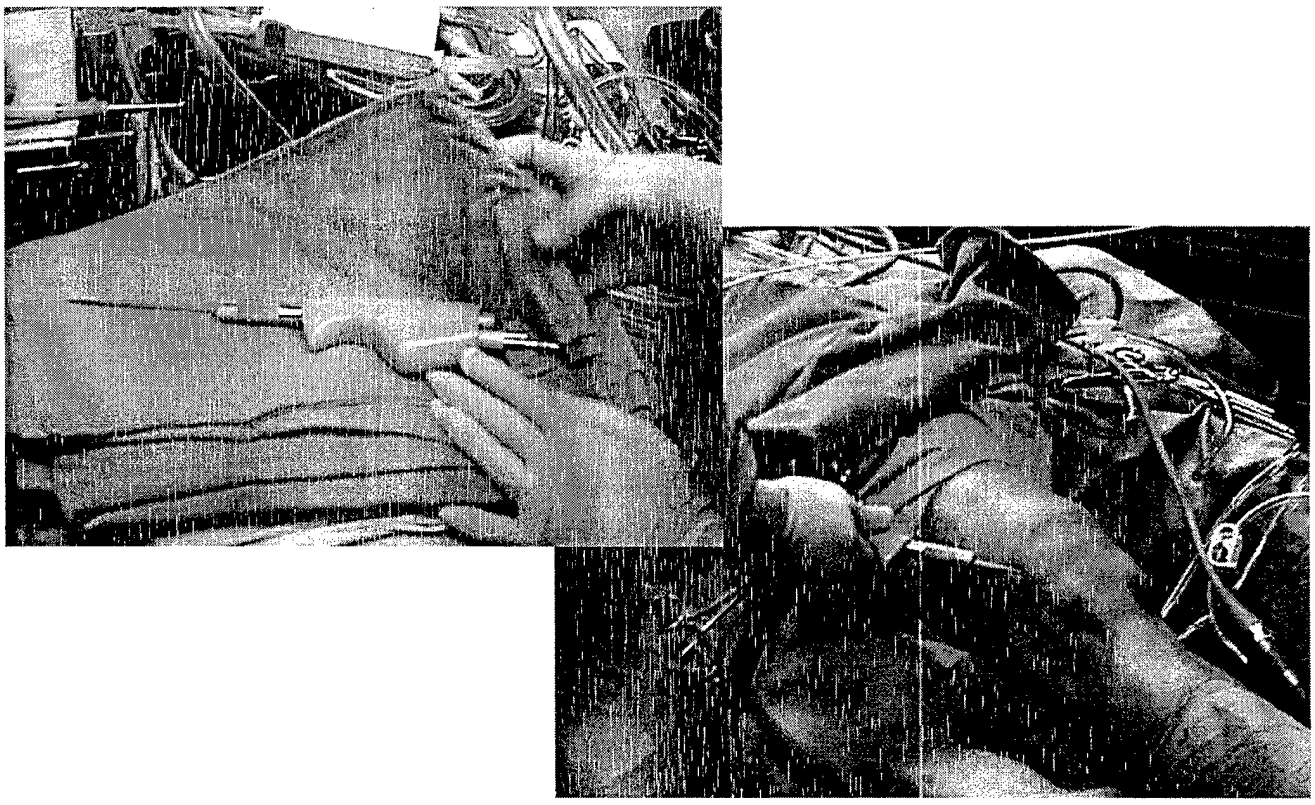
REPORTABLE OUTCOMES

Steiner CP, Sung G, Hahn JF, Gill IS; WEB Based Urological Surgery Archive, Journal of Endourology; Volume 13, Supplement 1, PS20-18, September 1999

U.S. Provisional Patent Application: The Electronic Surgical Record, Docket:26473/04015

CONCLUSIONS

The DME at this point has only been evaluated in the laboratory under specific guidelines. The question that was to be asked and answered was whether a small diameter fiber optic endoscope could provide enough visual information to be useful in a medical setting in the absence of other internal imaging methods. The answer to this question was a resounding yes. Typical endoscopes range in size from 10mm to 3.5mm and provide a view that is both clear and bright. Early attempts to reduce the size of an endoscope to 2mm using a bundled fiberoptic cable resulted in a poorly light unbalanced image that was all but unusable except for unusual circumstances. The DME that was developed for the CAMIS project shows tremendous promise in several surgical areas and will enable interventional procedures to be performed in a percutaneous anesthetic setting such as a medical office or field location. The reasons for this accomplishment and two-fold. The first, the fiberoptic endoscope dedicates more fibers for the transmission of the internal image back to the awaiting camera. This comes at a cost of reducing the number of fibers for transmission of light into the body cavity. This method is acceptable because of the second major accomplishment, digital processing of the video image. The method for processing the video image balances the light, sharpens the image and removes the moiré pattern common to fiber bundle images. The result of these techniques provides an endoscope suitable for intra-cavity imaging under a regional anesthetic.

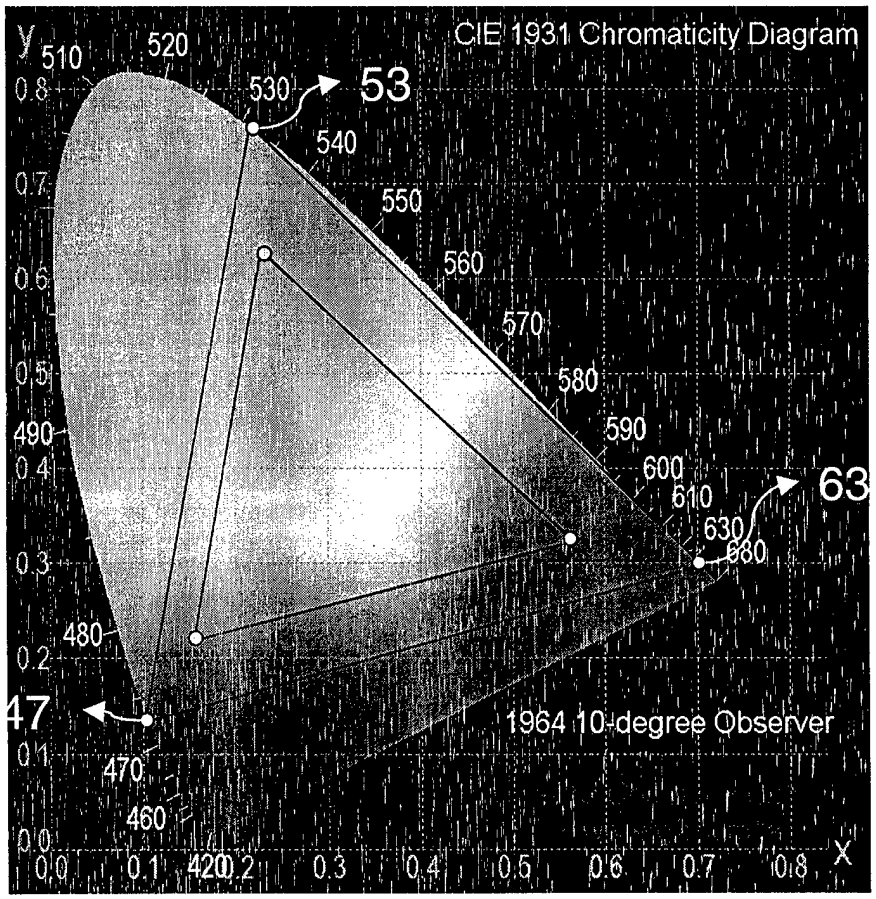


This device may have a significant impact on the move of surgical procedures from hospital operating rooms into lower cost ambulatory surgery centers and medical offices. In addition the device may obviate the need for screening orthopaedic MRI studies because the resulting images provide a direct view of the structure in question and provide it to the physician that needs to evaluate the problem.

Additional societal benefits from a quicker return to work may be difficult to quantify but are of equal importance when evaluating any minimally invasive surgical device.

The PRD has become the patient reference system of choice in the main operating rooms and ambulatory surgery centers of the Cleveland Clinic Foundation Health System. A user can reference information available from multiple sources about their patient using a simple medical record number search. The information available could be from Radiology, Pathology, Anesthesia or Surgery itself from a previous or current procedure. The simple user interface is intuitive enough to be used during a surgical procedure and has been demonstrated to be voice controllable when used in conjunction with the Computer Motion, Inc., Goleta California, Hermes™ system. The key evaluation of this system will occur when the full compliment of data interfaces is complete.

The full color PSD device was delivered during the final period of the project. A monochromatic version of the device was delivered slightly earlier but was not sufficient for clinical evaluation. The full color version was demonstrated in a laboratory setting with very positive results. The device was used to display historical patient information as well as real-time status variables collected with the PRD project component. The performance of the VRD was excellent. The figure below is a CIE Chromaticity Diagram with portrays the visual spectrum using the wavelength of light in nanometers as a measure. The entire diagram represents the theoretical limits of visible light. The center triangle represents the limits of most visual displays. The outer triangle represents the performance of the VRD. The quality of the VRD display appears more vibrant and realistic and this diagram explains the reason why.



REFERENCES

No references cited.

APPENDICES

A - Electronic Surgical Record, Provisional Patent Application Dkt No.: 26473-04015